General

Guideline Title

ACR Appropriateness Criteria® imaging for transcatheter aortic valve replacement.

Bibliographic Source(s)

Dill KE, George E, Rybicki FJ, Abbara S, Cummings K, Francois CJ, Gerhard-Herman MD, Gornik HL, Hanley M, Kalva SP, Kirsch J, Kramer CM, Majdalany BS, Moriarty JM, Oliva IB, Schenker MP, Strax R, Expert Panel on Vascular Imaging and Cardiac Imaging. ACR Appropriateness CriteriaÂ® imaging for transcatheter aortic valve replacement. [online publication]. Reston (VA): American College of Radiology (ACR); 2013. 12 p. [76 references]

Guideline Status

This is the current release of the guideline.

Recommendations

Major Recommendations

ACR Appropriateness Criteria®

Clinical Condition: Imaging for Transcatheter Aortic Valve Replacement

Variant 1: Pre-intervention planning at the aortic valve plane.

Radiologic Procedure	Rating	Comments	RRL*
CTA chest with contrast	9		
US echocardiography transesophageal	8		O
US echocardiography transthoracic resting	7		O
MRI heart function and morphology without contrast	6		O
MRI heart function and morphology without and with contrast	4,5,6 May be appropriate; 7,8,9 Usually appropriate	See discussion in text below under MRI heart function and morphology without and with contrast	O

*Relative

Radiologic Procedure	Rating	Comments	RRL*
without and with contrast		"Anticipated Exceptions."	
CT chest without contrast	5		
Aortography thoracic	3		
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative Radiation Level

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Variant 2: Pre-intervention planning in the supravalvular aorta and iliofemoral system.

Radiologic Procedure	Rating	Comments	RRL*
CTA abdomen and pelvis with contrast	9		
MRA abdomen and pelvis without and with contrast	7	See statement regarding contrast in text below under "Anticipated Exceptions."	O
CT abdomen and pelvis without contrast	6		
MRA abdomen and pelvis without contrast	5		O
Aortography abdomen and pelvis	3		
US intravascular aorta and iliofemoral system	3		O
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative Radiation Level

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Summary of Literature Review

Introduction/Background

Aortic stenosis (AS) has become the most frequent type of valvular heart disease in Europe and North America. It primarily presents as calcific AS in adults of advanced age (2%–7% of the population >65 years of age). This calcific disease progresses from the base of the cusps to the leaflets and eventually causes a reduction in leaflet motion and effective valve area without commissural fusion. A congenital malformation of the valve, most commonly the bicuspid aortic valve, may also result in stenosis and is more common in young adults. AS is a disease continuum with

no single value that defines severity; therefore, it is graded on the basis of a variety of hemodynamic and natural history data. According to current guidelines, severe AS is defined as an aortic valve area (AVA) <1.0 cm^2 (or <0.6 cm^2/m^2 body surface area), mean aortic valve pressure gradient >40 mm Hg, or an aortic jet velocity >4 m/s. Two-dimensional transthoracic echocardiography (TTE) is the standard for diagnosis and severity assessment through Doppler quantification of maximum jet velocity, mean transvalvular pressure gradient, and AVA by continuity equation.

Aortic valve replacement (AVR) is the definitive therapy for severe AS. It is indicated in those patients with severe AS who are symptomatic, undergoing coronary artery bypass graft or other cardiac surgery, have left ventricle (LV) systolic dysfunction defined as an ejection fraction <50%, are asymptomatic with abnormal exercise response, asymptomatic with critical AS (AVA <0.6 cm^2), or have a high likelihood of rapid progression. However, 32% to 48% of these patients do not undergo conventional AVR due to their advanced age, comorbidities, or prohibitive surgical risk. Aortic balloon valvuloplasty has been used in selected cases as a palliative measure when conventional surgery is contraindicated or for patients with symptomatic severe AS who require urgent, major noncardiac surgery with severe comorbidities. Treatment of such high surgical risk patients has been modified with the introduction of catheter-based implantation of a bioprosthetic aortic valve, referred to as transcatheter aortic valve replacement (TAVR).

In patients of high surgical risk, TAVR has been feasible using transfemoral, transapical, or, less commonly, subclavian or direct transaortic access. Once the access route is chosen, the transcatheter aortic valve prosthesis is positioned at the aortic annulus, which displaces the native aortic valve leaflets toward the aortic wall. The main procedure-related complications are cerebral vascular accident, heart block requiring new pacemaker, and vascular access-related complications. Trace or mild paravalvular aortic regurgitation (AR) is common in the majority of patients. More severe regurgitation can have impact on long-term survival. Even a mild degree of AR appears to affect prognosis. Percutaneous AVR provides hemodynamic results that are slightly superior to conventional bioprostheses. Most survivors experience significant health and quality of life improvement. The long-term durability of these valves still needs to be addressed.

Several prosthesis types are available for current clinical use with multiple second-generation devices in development. The self-expandable Medtronic CoreValve (Medtronic Inc, Minneapolis, MN, USA), which is available in 23 mm, 26 mm, 29 mm, and 31 mm sizes, as well as the balloon-expandable Edwards SAPIEN valve (Edwards Lifesciences Inc, Irvine, CA, USA), which is available in multiple models and sizes of 20 mm, 23 mm, 26 mm and 29 mm, are most commonly used. In the United States as of May 2013, only 23 mm and 26 mm Edwards SAPIEN valve prostheses are available.

Because transcatheter valvular procedures are characterized by lack of exposure of the operative field, image guidance is critical for preprocedural planning, intraoperative decision making, and follow-up. Such imaging determines a suitable access route prior to the procedure, appropriate sizing of the prosthetic valve, as well as additional information that is potentially helpful, such as chest wall deformity, intracardiac thrombus, degree of vascular tortuosity, valvular and vascular calcification, and appropriate fluoroscopic projection angles for exact orthogonal angles of the valve. Standard two-dimensional (2-D) imaging with conventional angiography and echocardiography are important for patient selection and procedural guidance. In addition, three-dimensional (3-D) imaging including computed tomography (CT), magnetic resonance imaging (MRI), 3-D echocardiography, and C-arm CT are increasingly used.

Planning at the aortic valve plane involves multiple measurements for accurate device sizing. These include measurements of the left ventricular outflow tract (LVOT) and interventricular septum, aortic annulus, sinuses of Valsalva, sinotubular junction, ascending aorta, coronary leaflets, and coronary annular-ostial distance. Preprocedural imaging at the annular plane contributes to outcome prediction through quantification and localization of aortic valve calcification. In addition, imaging for coexistent mitral valve disease, LV function, and coronary artery disease and to determine the best fluoroscopic projection for device deployment are essential data to optimize procedural success.

During TAVR, the prosthesis anchors according to the resistance of the subleaflet tissue. Undersizing the percutaneous valve increases the risk of prosthesis mismatch, transvalvular AR, and device migration or embolization. Oversizing can cause procedural difficulty, annular rupture, and underexpansion, which results in redundant leaflet tissue causing regional compressive and tensile stress that may contribute to transvalvular AR and a reduction in valve durability. The length of the aortic leaflet and the distance of the coronary ostia from the annulus should be considered when estimating the risk of ostial coronary occlusion when the native leaflets are crushed to the aortic wall by the valve deployment. The LVOT and septal anatomy must be evaluated for proper seating of the prosthesis to avoid embolization into the ventricle or aorta. Device manufacturer's guidelines recommend that implantation should not be performed if subaortic disease is sufficient to cause stenosis or if septal wall thickness is ≥17 mm.

Echocardiography and catheter-based angiography have been the standards for measuring the aortic annulus, and current device manufacturer's guidelines are based on transesophageal echocardiography (TEE) or TTE measurements. However, there is growing consensus that these 2-D measurements underestimate the aortic annular dimension because of its complex oval shape and the fact that these measurements might not always measure the maximum diameter passing through the center of the annulus but instead measure its tangent. Volumetric imaging can then be assessed in any plane, enabling accurate measurements of maximum, minimum, and mean diameters and circumference and area-derived diameter, though

the latter has been proposed as more relevant, considering that the oval-shaped annulus assumes a circular shape post-TAVR.

It is of paramount importance to assess the minimum lumen diameter of the iliofemoral system for transfemoral access route, the degree and distribution of atherosclerotic plaque and calcification, tortuosity and angulation, coarctation of the aorta, and high-risk features such as dissection, aneurysm, or complex atheroma. Presence of a patch in the LV or calcified pericardium, as well as inaccessible LV apex are contraindications to transapical approach and should be evaluated during planning. In patients whom trans-subclavian access is planned due to contraindications to transfemoral device delivery or angiography, CT or duplex ultrasound have been used to assess for tortuosity, diameter, and distribution of calcification, though there is no definite data comparing the different modalities. Commercially available suture-based vascular closure devices are used to close the arterial access site using the preclosure technique.

Pre-intervention Planning at the Aortic Valve Plane

Computed Tomography

Multidetector computed tomography (MDCT) provides high-spatial resolution, 3-D, and isotropic imaging of the aortic valve and aortic root and can contribute to the diagnosis and management of AS in a number of ways.

Noncontrast imaging can be used to evaluate valve calcification. CT has been shown to accurately detect and quantify aortic valve calcification with high reproducibility; however, as with echocardiography, the degree of aortic valve sclerosis can only be visually quantified in rough categories. Accurate characterization is important; it has been shown that the amount of valve calcification predicts the progression and clinical outcome of AS and is a predictor of pacemaker implantation after TAVR. The amount and distribution of calcium (assessed by the Agatston Score, volumetric quantification, or subjective semiquantitative metrics), with that on the aortic wall and valvular commissure being more significant, can predict noncircular deployment of prosthesis. This is important in decreasing the likelihood of paravalvular AR after TAVR and decreasing the need for additional procedures.

CT angiography (CTA) is used to assess valve anatomy, which allows direct visualization of the valve with a high degree of accuracy for direct planimetry of the AVA. In some patients, the aortic valve may be dysmorphic, and the orifice will be oriented in such a way that can deviate from the plane of the aortic annulus. However, with the multiplanar capability of CT it is possible to evaluate a plane that exactly corresponds to the orifice. Without such capability, choosing an incorrect plane for planimetry will result in either an overestimation or underestimation of the orifice area. Imaging methods that use hemodynamic data to estimate AVAs often show deviation from techniques that use anatomic visualization. In this context, CT has been shown to overestimate aortic valve opening areas compared with TTE, which uses the continuity equation to derive valve area. CT correlates well with TEE, which also uses direct visualization and planimetry of the aortic valve.

CT can reliably evaluate the distance between the aortic annulus and the inferior aspects of the lowest coronary ostia for subsequent prosthetic aortic valve implantation to avoid coronary obstruction by the implanted prosthesis.

Using retrospective electrocardiography-gating, the CTA acquisition can include a cine evaluation of valve function and size throughout the cardiac cycle. Despite high spatial resolution (0.5 mm), assessment of the valve can be limited secondary to the relatively low temporal resolution (>75 milliseconds). However, measurements from multiplanar reformatted CT data are well correlated with intraoperative measurements. The difference of the annular size from that of the prosthesis is predictive of paravalvular AR, with some data showing CT measures as more predictive than echocardiography.

Although a CT-based sizing approach would alter the echocardiography-derived sizing decision in 10% to 68% of cases depending on the diameter used, a pilot study demonstrated reduced incidence of paravalvular AR using a CT-based approach. The method of incorporating CT measurements into manufacturer-defined, echocardiography-based cutoffs for prosthesis sizing is unclear, and its effect on clinical outcomes should be further assessed.

Volumetric assessment of the aortic root from multiplanar reformatting and volume rendering assists in determining the optimal fluoroscopic projection orthogonal to the native valve plane for prosthesis deployment. In one study, MDCT predicted an excellent or satisfactory angle when correlated to angiographic images in 75% of cases. Software that integrates CT and catheter-based angiography data to help determine valve plane orientation is currently available. At experienced centers, 3-D MDCT aortic root reconstructions have become first-line methods to predict optimal implant projection. Eventually, four-dimensional (4-D)-coregistered CT could reduce the need for data derived from catheterization.

Contrast agents can often cause problems in TAVR candidates who have impaired renal function. High-pitch spiral CT imaging as well as wide-area detector axial CT with temporal uniformity are available with newer generation CT systems, allowing high-resolution imaging of large anatomical volumes in a short time, which reduces radiation exposure and contrast volume (total dose reported as low as 40 cc for an entire examination).

Echocardiography

Echocardiography is essential in identifying patients suitable for TAVR and in providing intraprocedural monitoring. Moreover, echocardiography is the primary modality for postprocedure follow-up. It is the most widely used method to measure the annulus and was considered as the reference method in the PARTNER Trial. Aortic annular measurements are typically performed in systole using the parasternal long axis view on TTE. Commissural and leaflet cusp calcification as detected on TEE correlates with postsurgical paravalvular AR.

Because the geometry of the annulus is ellipsoid, it results in a larger diameter in the coronal direction and a smaller diameter in the sagittal direction. Using a 2-D imaging technique can underestimate the maximal valve diameter, an observation shown with 2-D TTE and TEE in several studies. Two-dimensional TTE and TEE provided similar results for the aortic annulus diameter and morphologically similar measurements when compared to the sagittal diameter measured by MDCT. Several studies have demonstrated that TEE results in larger diameter measurements than TTE. Cut planes of the aortic annulus may explain this phenomenon; transthoracic parasternal and mid-esophageal acoustic windows do not necessarily oppose each other exactly. Although most measurements at the valve level can be made with the transthoracic approach, TEE is recommended when there is concern regarding the assessment of aortic root by TTE. Though there is high correlation between CT and 2-D echocardiographic annular measurements on corresponding planes, multiplanar reformatted CT measurements are significantly greater than those derived from 2-D TTE or TEE. Both TTE and TEE aortic annulus measurements can underestimate perioperative calibration, although this may be clinically insignificant as prostheses are routinely oversized.

Although the determination of the right coronary annular-ostial distance should be possible with 2-D TEE, measurement of the left coronary annular-ostial distance requires 3-D TEE or MDCT, since the right coronary artery ostium lies in a coronal plane that cannot be acquired by standard 2-D echocardiography.

TTE is the clinical reference standard to evaluate AS, although there is evidence that determination of the AVA as performed by TTE may underestimate orifice area and overestimate stenosis severity. According to the 2011 European Association of Echocardiography/American Society of Echocardiography recommendations for the use of echocardiography in new transcatheter interventions for valvular heart disease, there is no consensus regarding the reference standard imaging technique for annular sizing; although, from a practical perspective, TTE performs this task adequately in most patients.

Three-dimensional TTE and TEE enable short axis views of the annulus. However, the spatial resolution of 3-D TTE limits its use for annular measurements in the majority of cases. Initial studies with 3-D TEE demonstrate low variability and good correlation with corresponding views on CT. Three-dimensional TEE is probably most useful immediately following valve deployment, when the echocardiographer must rapidly and accurately assess the position and function of the valve including identifying the presence/severity of AR.

Magnetic Resonance Imaging

Cardiovascular magnetic resonance (CMR) provides highly accurate, low variability measurements of the aortic annulus for patients undergoing surgical AVR. Although there is a paucity of MR data for TAVR planning in comparison to that for CT, noncontrast MR demonstrates excellent correlation with CT-based TAVR measurements related to annular dimension with excellent intra- and interobserver correlation. A study with 24 patients showed no difference in the AVA for MRI planimetry, Doppler echocardiography, 3-D TTE, and catheterization. It has been suggested that CMR could be considered an alternative to CT in patients who cannot receive iodinated contrast agents, particularly for patients with renal insufficiency or in situations where detailed hemodynamic assessment of valvular regurgitation is required. CMR and CT in a recent study provided the necessary aortic and cardiac anatomical information for valve-in-valve TAVR planning.

MR approaches are limited when there is high-susceptibility artifact, magnetic field-incompatible devices, claustrophobia, and severe arrhythmia. Finally, the MR examination is substantially longer than the CT acquisition, and this can be problematic for patients with a poor clinical condition.

Catheter Arteriography

Invasive catheterization with fluoroscopic guidance estimates the orifice area on the basis of pressure gradients and cardiac output and hence provides a functional aortic orifice area. The reference standard for the orifice area is direct inspection. However, this is not feasible during TAVR.

To achieve accurate device positioning during TAVR, specific angiographic deployment angles perpendicular or orthogonal to the native aortic valve plane need to be used. Because patient anatomy varies, individualized assessment and understanding is necessary, which may require multiple orthogonal aortic root angiograms until a projection angle with the base of all aortic valve cusps/sinuses of Valsalva is on a straight line. Thus, angiography requires meticulous manipulation to avoid geometric distortion of the aortic annulus diameters. Aortography at the time of the procedure is considered necessary and complementary to prior imaging. However, the use of catheter angiography during the procedure in which the valve is deployed is not within the scope of this document, which evaluates preprocedure planning only.

Arteriography is a 2-D imaging technique with projections that may not adequately reflect the largest diameter and potentially pose calibration difficulties when measuring the annulus size. Limited studies show that angiographic annular dimensions from an AP view underestimate CT-derived

measurements and have high intraobserver and interobserver variability. Considering these limitations, catheter arteriography is not considered as a standalone modality for preprocedural planning. Improving the angiographic assessment of aortic annulus diameters can be accomplished with 3-D rotational angiography, which allows 3-D visualization of the aortic valve plane.

Traditional fluoroscopy with repeated aortic injections just before valve deployment is time-consuming, carries an increasing risk of nephrotoxicity as iodinated contrast material use increases, and increases radiation exposure. Moreover, this approach is often difficult in patients with unusual anatomy. Three-dimensional angiographic reconstructions from rotational C-arm fluoroscopic images can determine the optimal plane for device deployment faster and with lower contrast volume. Currently available software allows for overlay of the 3-D visualization onto fluoroscopic images to guide the procedure.

Pre-intervention Planning in the Supravalvular Aorta and Iliofemoral System

Computed Tomography

TAVR requires the introduction of an 18- to 24-Fr catheter-based system, and the femoral artery is most common approach. Thus, because of size criteria and the potential for vascular injury, the entire aorta plus the iliofemoral system are assessed. When CTA was performed as part of a TAVR research protocol, a minimum lumen diameter of 7 mm was required for inclusion to the studies. From a clinical perspective, TAVR can be performed in patients with smaller arteries, particularly when there is no or limited calcium. This target is likely to change with the availability of smaller sheaths. In some instances, when the iliofemoral vessels are inaccessible, retroperitoneally placed Dacron tube grafts can serve as a conduit for the delivery system. Image postprocessing tools can be used to assist in the assessment of lumen diameter, and 3-D volume rendering, maximum-intensity projections, and curved multiplanar reformations are integral to the assessment of tortuosity and minimum luminal diameter.

Concentric or horseshoe calcification is a relative contraindication for TAVR, especially in those with borderline vessel diameter. Incidental findings that affect the indication, approach, or TAVR timing, or findings that require further diagnostic workup (e.g., malignancy, aortic dissection, and aneurysm) are detected in a significant proportion of these patients.

CT with ultra-low dose intra-arterial contrast injection has been proposed as an alternative approach for pre-TAVR assessment in those at risk of contrast-induced nephropathy. Rapid acquisition CT imaging is available for assessment of the aorta and iliofemoral system, which can significantly reduce radiation exposure and contrast volume.

Catheter Angiography

Though catheter angiography allows assessment of luminal size, it provides limited evaluation of the arterial wall for plaque burden and calcification.

Magnetic Resonance Imaging

Contrast-enhanced magnetic resonance angiography (MRA) provides an alternative to CT for evaluation of the aorta and iliofemoral arteries. Caution should be exercised in patients with severe renal dysfunction due to increased risk of nephrogenic systemic fibrosis.

Intravascular Ultrasound

Surface ultrasound is often used to identify an optimal puncture site and to gain access to the femoral artery. However, because of the technical limitation of sonography, this approach is insufficient to comprehensively assess arterial size, calcification, and tortuosity of the iliofemoral system and the aorta. Although there is little or no data regarding the utility of intravascular ultrasound for TAVR planning, studies in abdominal aortic aneurysm subjects have provided reliable information of aortoiliofemoral anatomy, especially luminal dimension, presence of and morphology of atherosclerotic plaque, and calcification.

Summary

- Similar to the process of developing guidelines for the recently U.S. Food and Drug Administration (FDA)-approved TAVR procedure, the role of imaging should be guided by expert consensus.
- Many clinical studies regarding the management of AS have been based on echocardiography and have shaped guidelines for surgical treatment. However, increasing evidence reveals that TTE tends to underestimate the AVA and overestimate stenosis severity.
- CT constitutes a central tool for preprocedural TAVR planning by providing crucial information about the LVOT, aortic valve, aortic root anatomy, thoracoabdominal aorta, and peripheral arteries.
- Current CT scanners permit planimetry of AVAs with high accuracy and may be of clinical use to determine stenosis severity in selected patients, especially when other methods fail.
- The superior spatial resolution of CT (0.5 mm) allows for accurate anatomic evaluation of the aortic valve and extent of calcification. Evidence exists that there is decreased incidence of paravalvular AR using a CT-based approach.

- Radiation exposure and iodine injection are important MDCT limitations, but the modality may provide useful additional information such as the anatomy of the coronary arteries and AVA as well as anatomy and the plane of the valve and the distribution of aortic valve calcifications.
- There is a paucity of data on the role of CMR for TAVR planning and follow-up, with positive preliminary results in limited circumstances.
- Echocardiography is the most widely used method for measuring the aortic annulus. Although there is no consensus regarding the reference standard imaging technique for annular sizing, TTE performs this task adequately in most patients.

Anticipated Exceptions

Nephrogenic systemic fibrosis (NSF) is a disorder with a scleroderma-like presentation and a spectrum of manifestations that can range from limited clinical sequelae to fatality. It appears to be related to both underlying severe renal dysfunction and the administration of gadolinium-based contrast agents. It has occurred primarily in patients on dialysis, rarely in patients with very limited glomerular filtration rate (GFR) (i.e., <30 mL/min/1.73 m^2), and almost never in other patients. There is growing literature regarding NSF. Although some controversy and lack of clarity remain, there is a consensus that it is advisable to avoid all gadolinium-based contrast agents in dialysis-dependent patients unless the possible benefits clearly outweigh the risk, and to limit the type and amount in patients with estimated GFR rates <30 mL/min/1.73 m^2. For more information, see the American College of Radiology (ACR) Manual on Contrast Media (see the "Availability of Companion Documents" field).

Abbreviations

- CTA, computed tomography angiography
- MRA, magnetic resonance angiography
- MRI, magnetic resonance imaging
- US, ultrasound

Relative Radiation Level Designations

Relative Radiation Level*	Adult Effective Dose Estimate Range	Pediatric Effective Dose Estimate Range
O	0 mSv	0 mSv
	<0.1 mSv	<0.03 mSv
	0.1-1 mSv	0.03-0.3 mSv
	1-10 mSv	0.3-3 mSv
	10-30 mSv	3-10 mSv
	30-100 mSv	10-30 mSv
*RRL assignments for some of the examinations cannot be made, because the actual patient doses in these procedures vary as a function of a number of factors (e.g., region of the body exposed to ionizing radiation, the imaging guidance that is used). The RRLs for these examinations are designated as "Varies."		

Clinical Algorithm(s)

Algorithms were not developed from criteria guidelines.

Scope

Disease/Condition(s)

Aortic stenosis requiring transcatheter aortic valve replacement

Guideline Category

Evaluation

Clinical Specialty

Cardiology

Internal Medicine

Radiology

Thoracic Surgery

Intended Users

Health Plans

Hospitals

Managed Care Organizations

Physicians

Utilization Management

Guideline Objective(s)

To evaluate the appropriateness of preprocedural imaging for transcatheter aortic valve replacement

Target Population

Patients with severe aortic stenosis requiring transcatheter aortic valve replacement

Interventions and Practices Considered

1. Computed tomography angiography (CTA)
    - Chest with contrast
    - Abdomen and pelvis with contrast
2. Ultrasound (US)
    - Echocardiography transesophageal
    - Echocardiography transthoracic resting
    - Intravascular aorta and iliofemoral system
3. Magnetic resonance imaging (MRI) heart function and morphology
    - Without contrast
    - Without and with contrast
4. Magnetic resonance angiography (MRA) abdomen and pelvis
    - Without and with contrast
    - Without contrast
5. Computed tomography (CT)
    - Chest without contrast
    - Abdomen and pelvis without contrast
6. Aortography
    - Thoracic
    - Abdomen and pelvis

Major Outcomes Considered

Utility and accuracy of radiologic examinations for preprocedural evaluation

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Literature Search Procedure

Staff will search in PubMed only for peer reviewed medical literature for routine searches. Any article or guideline may be used by the author in the narrative but those materials may have been identified outside of the routine literature search process.

The Medline literature search is based on keywords provided by the topic author. The two general classes of keywords are those related to the condition (e.g., ankle pain, fever) and those that describe the diagnostic or therapeutic intervention of interest (e.g., mammography, MRI).

The search terms and parameters are manipulated to produce the most relevant, current evidence to address the American College of Radiology Appropriateness Criteria (ACR AC) topic being reviewed or developed. Combining the clinical conditions and diagnostic modalities or therapeutic procedures narrows the search to be relevant to the topic. Exploding the term "diagnostic imaging" captures relevant results for diagnostic topics.

The following criteria/limits are used in the searches.

1. Articles that have abstracts available and are concerned with humans.
2. Restrict the search to the year prior to the last topic update or in some cases the author of the topic may specify which year range to use in the search. For new topics, the year range is restricted to the last 10 years unless the topic author provides other instructions.
3. May restrict the search to Adults only or Pediatrics only.
4. Articles consisting of only summaries or case reports are often excluded from final results.

The search strategy may be revised to improve the output as needed.

Number of Source Documents

The total number of source documents identified as the result of the literature search is not known.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Strength of Evidence Key

Category 1 - The conclusions of the study are valid and strongly supported by study design, analysis, and results.

Category 2 - The conclusions of the study are likely valid, but study design does not permit certainty.

Category 3 - The conclusions of the study may be valid, but the evidence supporting the conclusions is inconclusive or equivocal.

Category 4 - The conclusions of the study may not be valid because the evidence may not be reliable given the study design or analysis.

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

The topic author drafts or revises the narrative text summarizing the evidence found in the literature. American College of Radiology (ACR) staff draft an evidence table based on the analysis of the selected literature. These tables rate the strength of the evidence (study quality) for each article included in the narrative text.

The expert panel reviews the narrative text, evidence table, and the supporting literature for each of the topic-variant combinations and assigns an appropriateness rating for each procedure listed in the table. Each individual panel member assigns a rating based on his/her interpretation of the available evidence.

More information about the evidence table development process can be found in the ACR Appropriateness Criteria® Evidence Table Development document (see the "Availability of Companion Documents" field).

Methods Used to Formulate the Recommendations

Expert Consensus (Delphi)

Description of Methods Used to Formulate the Recommendations

Rating Appropriateness

The appropriateness ratings for each of the procedures included in the Appropriateness Criteria topics are determined using a modified Delphi methodology. A series of surveys are conducted to elicit each panelist's expert interpretation of the evidence, based on the available data, regarding the appropriateness of an imaging or therapeutic procedure for a specific clinical scenario. American College of Radiology (ACR) staff distribute surveys to the panelists along with the evidence table and narrative. Each panelist interprets the available evidence and rates each procedure. The surveys are completed by panelists without consulting other panelists. The appropriateness rating scale is an ordinal scale that uses integers from 1 to 9 grouped into three categories: 1, 2, or 3 are in the category "usually not appropriate"; 4, 5, or 6 are in the category "may be appropriate"; and 7, 8, or 9 are in the category "usually appropriate." Each panel member assigns one rating for each procedure for a clinical scenario. The ratings assigned by each panel member are presented in a table displaying the frequency distribution of the ratings without identifying which members provided any particular rating.

If consensus is reached, the median rating is assigned as the panel's final recommendation/rating. Consensus is defined as eighty percent (80%) agreement within a rating category. A maximum of three rounds may be conducted to reach consensus. Consensus among the panel members must be achieved to determine the final rating for each procedure.

If consensus is not reached, the panel is convened by conference call. The strengths and weaknesses of each imaging procedure that has not reached consensus are discussed and a final rating is proposed. If the panelists on the call agree, the rating is proposed as the panel's consensus. The document is circulated to all the panelists to make the final determination. If consensus cannot be reached on the call or when the document is circulated, "No consensus" appears in the rating column and the reasons for this decision are added to the comment sections.

This modified Delphi method enables each panelist to express individual interpretations of the evidence and his or her expert opinion without excessive influence from fellow panelists in a simple, standardized and economical process. A more detailed explanation of the complete process can be found in additional methodology documents found on the ACR Web site (see also the "Availability of Companion Documents" field).

Rating Scheme for the Strength of the Recommendations

Not applicable

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

Internal Peer Review

Description of Method of Guideline Validation

Criteria developed by the Expert Panels are reviewed by the American College of Radiology (ACR) Committee on Appropriateness Criteria.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The recommendations are based on analysis of the current literature and expert panel consensus.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Selection of appropriate radiologic imaging procedures to aid in preprocedural planning for transcatheter aortic valve replacement

Potential Harms

- The main procedure-related complications of transcatheter aortic valve replacement are cerebral vascular accident, heart block requiring new pacemaker, and vascular access-related complications. Trace or mild paravalvular aortic regurgitation (AR) is common in the majority of patients.
- Undersizing the percutaneous valve increases the risk of prosthesis mismatch, transvalvular AR, and device migration or embolization. Oversizing can cause procedural difficulty, annular rupture, and underexpansion, which results in redundant leaflet tissue causing regional compressive and tensile stress that may contribute to transvalvular AR and a reduction in valve durability. The length of the aortic leaflet and the distance of the coronary ostia from the annulus should be considered when estimating the risk of ostial coronary occlusion when the native leaflets are crushed to the aortic wall by the valve deployment. The left ventricular outflow tract and septal anatomy must be evaluated for proper seating of the prosthesis to avoid embolization into the ventricle or aorta. Device manufacturer's guidelines recommend that implantation should not be performed if subaortic disease is sufficient to cause stenosis or if septal wall thickness is ≥17 mm.
- Traditional fluoroscopy with repeated aortic injections just before valve deployment is time-consuming, carries an increasing risk of nephrotoxicity as iodinated contrast material use increases, and increases radiation exposure. Moreover, this approach is often difficult in patients with unusual anatomy.
- Contrast-enhanced magnetic resonance angiography (MRA) provides an alternative to computed tomography for evaluation of the aorta and iliofemoral arteries. Caution should be exercised in patients with severe renal dysfunction due to increased risk of nephrogenic systemic fibrosis.

Gadolinium-based Contrast Agents

Nephrogenic systemic fibrosis (NSF) is a disorder with a scleroderma-like presentation and a spectrum of manifestations that can range from limited clinical sequelae to fatality. It appears to be related to both underlying severe renal dysfunction and the administration of gadolinium-based contrast agents. It has occurred primarily in patients on dialysis, rarely in patients with very limited glomerular filtration rate (GFR) (i.e., <30 mL/min/1.73 m^2), and almost never in other patients. Although some controversy and lack of clarity remain, there is a consensus that it is advisable to avoid all gadolinium-based contrast agents in dialysis-dependent patients unless the possible benefits clearly outweigh the risk, and to limit the

type and amount in patients with estimated GFR rates <30 mL/min/1.73 m^2. For more information, please see the American College of Radiology (ACR) Manual on Contrast Media (see the "Availability of Companion Documents" field).

Relative Radiation Level (RRL)

Potential adverse health effects associated with radiation exposure are an important factor to consider when selecting the appropriate imaging procedure. Because there is a wide range of radiation exposures associated with different diagnostic procedures, a relative radiation level indication has been included for each imaging examination. The RRLs are based on effective dose, which is a radiation dose quantity that is used to estimate population total radiation risk associated with an imaging procedure. Patients in the pediatric age group are at inherently higher risk from exposure, both because of organ sensitivity and longer life expectancy (relevant to the long latency that appears to accompany radiation exposure). For these reasons, the RRL dose estimate ranges for pediatric examinations are lower as compared to those specified for adults. Additional information regarding radiation dose assessment for imaging examinations can be found in the ACR Appropriateness Criteria® Radiation Dose Assessment Introduction document (see the "Availability of Companion Documents" field).

Contraindications

Contraindications

- Presence of a patch in the left ventricle (LV) or calcified pericardium, as well as inaccessible LV apex, are contraindications to transapical approach and should be evaluated during planning.
- Concentric or horseshoe calcification is a relative contraindication for transcatheter aortic valve replacement (TAVR), especially in those with borderline vessel diameter.

Qualifying Statements

Qualifying Statements

The American College of Radiology (ACR) Committee on Appropriateness Criteria and its expert panels have developed criteria for determining appropriate imaging examinations for diagnosis and treatment of specified medical condition(s). These criteria are intended to guide radiologists, radiation oncologists, and referring physicians in making decisions regarding radiologic imaging and treatment. Generally, the complexity and severity of a patient's clinical condition should dictate the selection of appropriate imaging procedures or treatments. Only those examinations generally used for evaluation of the patient's condition are ranked. Other imaging studies necessary to evaluate other co-existent diseases or other medical consequences of this condition are not considered in this document. The availability of equipment or personnel may influence the selection of appropriate imaging procedures or treatments. Imaging techniques classified as investigational by the U.S. Food and Drug Administration (FDA) have not been considered in developing these criteria; however, study of new equipment and applications should be encouraged. The ultimate decision regarding the appropriateness of any specific radiologic examination or treatment must be made by the referring physician and radiologist in light of all the circumstances presented in an individual examination.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Living with Illness

IOM Domain

Effectiveness

Identifying Information and Availability

Bibliographic Source(s)

Dill KE, George E, Rybicki FJ, Abbara S, Cummings K, Francois CJ, Gerhard-Herman MD, Gornik HL, Hanley M, Kalva SP, Kirsch J, Kramer CM, Majdalany BS, Moriarty JM, Oliva IB, Schenker MP, Strax R, Expert Panel on Vascular Imaging and Cardiac Imaging. ACR Appropriateness CriteriaÂ® imaging for transcatheter aortic valve replacement. [online publication]. Reston (VA): American College of Radiology (ACR); 2013. 12 p. [76 references]

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2013

Guideline Developer(s)

American College of Radiology - Medical Specialty Society

Source(s) of Funding

The American College of Radiology (ACR) provided the funding and the resources for these ACR Appropriateness Criteria®.

Guideline Committee

Committee on Appropriateness Criteria, Expert Panels on Vascular Imaging and Cardiac Imaging

Composition of Group That Authored the Guideline

Panel Members: Karin E. Dill, MD (*Principal Author and Panel Vice-chair [Vascular]*); Elizabeth George, MBBS (*Research Author*); Frank J. Rybicki, MD, PhD (*Panel Chair [Vascular]*); Suhny Abbara, MD (*Panel Vice-chair [Cardiac]*); Kristopher Cummings, MD; Christopher J. Francois, MD; Marie D. Gerhard-Herman, MD; Heather L. Gornik, MD; Michael Hanley, MD; Sanjeeva P. Kalva, MD; Jacobo Kirsch, MD; Christopher M. Kramer, MD; Bill S. Majdalany, MD; John M. Moriarty, MB, BCh; Isabel B. Oliva, MD; Matthew P. Schenker, MD; Richard Strax, MD

Financial Disclosures/Conflicts of Interest

Not stated

Guideline Status

This is the current release of the guideline.

Guideline Availability

Electronic copies: Available from the American College of Radiology (ACR) Web site.

Print copies: Available from the American College of Radiology, 1891 Preston White Drive, Reston, VA 20191. Telephone: (703) 648-8900.

Availability of Companion Documents

The following are available:

- ACR Appropriateness Criteria®. Overview. Reston (VA): American College of Radiology; 2013 Nov. 3 p. Electronic copies: Available in Portable Document Format (PDF) from the American College of Radiology (ACR) Web site.
- ACR Appropriateness Criteria®. Literature search process. Reston (VA): American College of Radiology; 2013 Apr. 1 p. Electronic copies: Available in PDF from the ACR Web site.
- ACR Appropriateness Criteria®. Evidence table development – diagnostic studies. Reston (VA): American College of Radiology; 2013 Nov. 3 p. Electronic copies: Available in PDF from the ACR Web site.
- ACR Appropriateness Criteria®. Radiation dose assessment introduction. Reston (VA): American College of Radiology; 2013 Nov. 3 p. Electronic copies: Available in PDF from the ACR Web site.
- ACR Appropriateness Criteria®. Manual on contrast media. Reston (VA): American College of Radiology; 90 p. Electronic copies: Available in PDF from the ACR Web site.
- ACR Appropriateness Criteria®. Procedure information. Reston (VA): American College of Radiology; 2013 Apr. 1 p. Electronic copies: Available in PDF from the ACR Web site.
- ACR Appropriateness Criteria® imaging for transcatheter aortic valve replacement. Evidence table. Reston (VA): American College of Radiology; 2013. 36 p. Electronic copies: Available from the ACR Web site.

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on March 7, 2014.

Copyright Statement

Disclaimer

NGC Disclaimer

All guidelines summarized by NGC and hosted on our site are produced under the auspices of medical specialty societies, relevant professional associations, public or private organizations, other government agencies, health care organizations or plans, and similar entities.

Guidelines represented on the NGC Web site are submitted by guideline developers, and are screened solely to determine that they meet the NGC Inclusion Criteria which may be found at http://www.guideline.gov/about/inclusion-criteria.aspx.

NGC, AHRQ, and its contractor ECRI Institute make no warranties concerning the content or clinical efficacy or effectiveness of the clinical practice guidelines and related materials represented on this site. Moreover, the views and opinions of developers or authors of guidelines represented on this site do not necessarily state or reflect those of NGC, AHRQ, or its contractor ECRI Institute, and inclusion or hosting of guidelines in NGC may not be used for advertising or commercial endorsement purposes.

Readers with questions regarding guideline content are directed to contact the guideline developer.